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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,183	03/16/2001	Robert W. Kreis	CV-0275	5218
26079 7590 09/11/2007 BRISTOL-MYERS SQUIBB COMPANY 100 HEADQUARTERS PARK DRIVE SKILLMAN, NJ 08558			EXAMINER SHEIKH, HUMERA N	
			ART UNIT 1615	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/719,183	<b>Applicant(s)</b> KREIS ET AL.	
	<b>Examiner</b> Humera N. Sheikh	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 9-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114, the Amendment and Applicant's Arguments/Remarks, all filed 06/26/07 is acknowledged.

Claims 1 and 9-16 are pending in this action. Claims 1 and 15 have been amended. Claims 2-8 have previously been cancelled. Claims 1 and 9-16 are rejected.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/26/07 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant in their response filed 06/26/07, has amended the claims to recite that “the wound dressing *be left in place for a period of time until after* epithelial outgrowth and vertical wicking into the dressing *occur*”. The limitation of a period of time “until after” epithelial outgrowth and vertical wicking occur introduces new matter into the instant claims. Applicant has not provided ample support for the amended claim language. A review of the instant specification does not demonstrate support for the language as now claimed by Applicant. Thus, the claim language reciting “until after” epithelial outgrowth and vertical wicking occur introduces a new concept not disclosed in the original specification.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlisle (U.S. Pat. No. 3,824,996) in view of Dyer *et al.* (U.S. Pat. No. 5,899,893) and further in view of Bernardin *et al.* (U.S. Pat. No. 5,124,197).**

◇The instant invention is drawn to a method of treating an acute wound using a wound dressing as a substitute for a biological dressing or skin graft comprising the steps of:

- a) applying the wound dressing to the wound; and
- b) allowing the wound dressing to adhere to the wound and be left in place for a period of time until after epithelial outgrowth and vertical wicking into the dressing occur, wherein the wound dressing comprises highly absorbent fibers.

◇The instant invention is also drawn to a method of treating an acute wound using a wound dressing comprising highly absorbent fibers that can absorb at least 25 g/g of deionized water comprising the steps of:

- a) applying the wound dressing to the wound;
- b) allowing the wound dressing to become adhered to the wound;
- c) leaving the dressing in place until it dries out to form a crust; and
- d) removing the dressing once the wound has healed.

◇The instant invention is also drawn to a method for substituting a wound dressing comprising highly absorbent fibers that can absorb at least 25 g/g of deionized water for a biological dressing comprising the steps of:

- a) applying the wound dressing to a wound that would otherwise be treated using a biological dressing; and

b) allowing the wound dressing to adhere to the wound and be left in place for a period of time until after epithelial outgrowth and vertical wicking into the dressing occur, wherein the wound dressing comprises highly absorbent fibers.

**Carlisle ('996)** teaches highly absorbent pressure dressings for wounds substantially constructed from cellulosic, fibrous material formed in thin layers and adapted to be applied and affixed to curved surfaces of the human body (see claims and Abstract).

According to Carlisle, the dressings have a finely porous, highly dense fibrous construction which provides the dual advantages of dispersing absorbed exudates to a low interlayer adhesion level, and preventing healing tissues from becoming entangled with the dressing's fibrous material (col. 3, lines 53-67). Carlisle teaches the significance of speed of absorption, direction of absorption and the length of wicking (col. 4, lines 1-14). The chart at column 4 demonstrates that the dressing of Carlisle absorbs fluid steadily and continuously (i.e., wicking) (see col. 4, lines 15-55).

Carlisle teaches that the dressing layer materials can absorb distilled water *vertically* against gravity continuously for more than 5 hours (see claim 4). Carlisle also teaches that the dressing, when affixed and held in place with retaining material, adapts to exert relatively even pressure on the wound surface which tends to improve the quality of the repair tissue formed during healing (claim 17).

The wound dressings can be applied to wounds, such as burns (col. 2, lines 63-67).

Suitable dressing materials taught includes hard and soft wood pulp (col. 5, lines 19-22) and fibrous dense cellulose materials (see claims 1, 5, 6, 18).

With regards to the claim limitation 'for a period of time until after epithelial outgrowth and vertical wicking occur' recited in instant claim 1, the Examiner notes that this limitation does not impart patentable weight to the claims. The limitation is relative in terms of the time required in which epithelial outgrowth and/or vertical wicking occurs since the limitation fails to set forth any specific time or duration parameters that is required for epithelial outgrowth and vertical wicking to occur. With regards to the amount of water (25 g/g) absorbed claimed in claims 12-15, Carlisle does not teach absorbing at least 25 g/g of deionized water. However, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In *Re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts through routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. The particular method of treating an acute wound using a wound dressing and applying the wound dressing to the wound would be obvious in view of the disclosure of Carlisle. Carlisle clearly teaches highly absorbent pressure dressings for wounds, such as burns, constructed from cellulosic, fibrous material, whereby the dressings are applied and affixed to curved surfaces of the human body.

In any event, *Dyer et al.* ('893) are relied upon for their teaching of absorbent articles, such as wound dressings, having a vertical wicking capability of at least about 30 g/g, more preferably at least about 40 g/g. Particularly preferred foam absorbents will wick at least about

45 g/g. The foam absorbents of the invention wick a high capacity of the test fluid to a particular height at equilibrium (see reference column 1, lines 11-19); (col. 2, line 45); (col. 7, lines 41-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the absorbent articles of Dyer *et al.* within the teachings of Carlisle. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Dyer *et al.* teach absorbent articles, particularly wound dressings and teach that their absorbent articles are able to wick at a high capacity at equilibrium, such as a vertical wicking capability of at least about 30 g/g, more preferably at least about 40 g/g and even at least about 45 g/g. The expected result would be a highly absorbent wound dressing that is beneficially used for the treatment of acute wounds.

**Bernardin *et al.* ('197)** are relied upon for the teaching of an absorbent web formed from inflated cellulose fibers whereby the web possesses improved vertical wicking properties (see col. 1, line 6 – col. 2, line 30); (col. 3, lines 16-28) and Abstract. The absorbent webs are suitable for use in forming absorbent products, such as dressings, incontinence products, feminine pads and the like (col. 6, lines 41-46). Suitable fibers used in the invention include natural fibers, such as wood fibers, cotton linters and cotton staple (col. 3, lines 46-58).

Bernardin *et al.* teach that as a general rule, the vertical wicking properties of a web will be considered improved when the web exhibits at least about a 20 percent increase in initial vertical wicking rate, vertical wicking capacity (at 15 or 30 minutes) or vertical fluid distribution (at a distance between nine and eighteen cm) when compared to a similar web (col. 4, lines 36-52).



Bernardin *et al.* teach that the improved vertical wicking properties of the webs allows fluid to be vertically wicked from one particular area of the web to another remote location on the web. The absorbent web is able to transport fluid from one location on the web to another location on the web, based on the improved vertical wicking properties (col. 7, lines 8-40).

It would have been obvious to incorporate the absorbent cellulose fibers that exhibit improved wicking properties within the highly absorbent pressure dressing of Carlisle. One of ordinary skill in the art would do so with a reasonable expectation of success because Bernardin *et al.* teach an absorbent web made of cellulosic fibers, for use in absorbent products such as dressings and teach that the vertical wicking properties allows the absorbent web to transport fluid from one location on the web to another location on the web, thus increasing the absorbent capacity of the absorbent web.

Given the teachings of Carlisle, Dyer *et al.* and Bernardin *et al.* delineated above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

Applicant's arguments filed 06/26/07 have been fully considered, but were not found to be persuasive.

- **35 U.S.C. §103(a) Rejection of claims 1 and 9-16 over Carlisle (U.S. Pat. No. 3,824,996) in view of Dyer et al. (U.S. Pat. No. 5,899,893):**

Applicant argued, "Carlisle is concerned with pressure dressings. According to Carlisle, pressure dressings are fundamental in the preparation of wounds for skin grafting. Carlisle does

not consider his dressing as a substitute for a biological dressing, but rather as a preparation for it. Carlisle, would not, therefore, motivate the person of ordinary skill to use a fibrous dressing as a substitute for a biological dressing. Further, dressings of Carlisle are dense, laminar dressings that wick laterally and bar the movement of exudates perpendicular to the plane of the dressing.”

Applicant’s arguments have been considered, but were not found persuasive. Carlisle teaches highly absorbent pressure dressings for wounds substantially constructed from cellulosic, fibrous material formed in thin layers and adapted to be applied and affixed to curved surfaces of the human body (see claims and Abstract). The fact that Applicants dressing can be used as a substitute for biological dressings does not provide for a patentable distinction over the wound dressings of the art. The Carlisle wound dressings are formed of the same materials as that of Applicant’s dressing.

Applicant argued, “Carlisle does not teach that the dressing is left in place or vertical wicking and does not suggest that there would be any advantage in vertical wicking”.

This argument was not persuasive. Carlisle recognizes that their wound dressing can be left on the skin for extended periods of time, such as two or more weeks, if desired (col. 3, lines 54-67). Applicants desire that their wound dressing is left in place, however this step does not impart any unexpected results or a patentable distinction over the Carlisle reference teachings. With regard to vertical wicking, Carlisle teach that speed and direction of absorption and length of wicking is important for their dressing. While vertical wicking is not explicitly discussed, the reference of Bernardin et al. is relied upon for the teaching of absorbent webs formed from

cellulose fibers, used in dressings, whereby the absorbent webs demonstrate improved vertical wicking properties. Thus, this limitation has been met.

Applicant argued, "The Action relies on Dyer, et al. to supply the deficiencies of Carlisle. However, there must be a suggestion in Carlisle to do so. Carlisle is concerned with pressure dressings that have limited compressibility. The dressing material of Dyer is foam, and it is well known that foams are highly compressible. Thus, a person having ordinary skill in the art would not substitute the foam of Dyer et al. for the lamellar dressing of Carlisle in order to improve the Carlisle dressing. Dyer does not demonstrate vertical wicking."

These arguments were not found persuasive. While Carlisle teach lateral wicking, rather than vertical wicking, Dyer et al. are relied upon to demonstrate that it is well known in the art to employ absorbent articles, such as wound dressings that have vertical wicking capability of at least about 30 g/g. Applicant's argument that "Carlisle teaches limited compressibility pressure dressings whereas Dyer is directed to a highly compressible foam" was not persuasive since both references are directed to highly absorbent articles used for wound dressing applications. Thus, this is a sufficient criteria to combine the references. Applicants stated that the "wicking in Dyer is the wicking of a vertically held strip of a test material against gravity." Thus, the Examiner has now relied on the tertiary reference of Bernardin et al. Bernardin et al. is relied upon for the teaching of absorbent webs formed from cellulose fibers, used in dressings, whereby the absorbent webs demonstrate improved vertical wicking properties. The improved vertical wicking properties allow for transport of fluid from one location on the web to another remote location, thus providing for increased absorbent capacity of the absorbent web.

Given the explicit teachings of the cited art of record, the instant invention when taken as a whole, would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Conclusion***

--No claims are allowed at this time.

**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

September 03, 2007

  
HUMERA N. SHEIKH  
PRIMARY EXAMINER